

REMARKS/ARGUMENTS

The Status of the Claims.

Claims 1 to 3, 5 to 16 and 20 to 24 are currently pending. Claims 4, and 17 to 19 have been previously cancelled. No claims are amended herein.

35 U.S.C. §102.

Claims 1, 2, 5, 6, 10 to 12, and 20 to 24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Grassetti (U.S. 4,378,364), as evidenced by Barber (5,662,896) and Tagawa (Current Pharm. Design 6:681 (2000)). Applicants traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, "all limitations of the claim are found in the reference, or 'fully met' by it." *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781, 789 (Fed. Cir. 1983).

Applicants stand by remarks and arguments of previous Responses with regard to this continued rejection. Applicants note that this same rejection was presented in the final Office Action of May 18, 2007. Applicants Argued against the rejection in the Response of July 25, 2007, page 11. The rejection was further argued in the Request for Review of October 18, 2008, and the Decision in the matter was in the favor of Applicant. Applicants are perplexed that this line of argument continues when it has been objectively shown and confirmed that Grassetti '364 does not anticipate the present claims.

Applicants again note that Grassetti '364 does not teach all limitations of the claims, and again note that the cited evidence of record actually supports the fact that not all cancer patients are in need of immune response modulation.

Grassetti '364 does not teach at least identifying an individual in need of immune response modulation. At section 4 of the present Action, the method step of "'identifying an individual in need of immune response modulation' is [allegedly] inherently met by the method of treating cancer patients ... as all cancer patients are recognized as 'in need of immune response modulation' see abstract in Tagawa and columns 1-2 in Berber et al."

Emphasis added. Applicants refuse to take Official Notice of this interpretation of the cited references.

Applicants have previously shown that these references actually stand for the principle that not all cancer patients are in need of immune modulation. See, e.g., Response of July 22, 2008, bottom of page 7. For example, Tagawa, Figure 1, shows how an unmodulated immune system normally works with, e.g., natural antigen presenting cells (APCs) activating cytotoxic T-lymphocytes (CTLs) to provide a normal CTL-mediated unmodulated immune response against a tumor *in vivo*. Barber, at the cited columns 1 and 2, makes it clear that cancer patients are not necessarily in need of immune modulation. For example, at column 1, line 35, Barber suggests that 30% of patients treated with surgery alone will have no recurrence. The continued allegation that "all cancer patients are recognized as in need of immune response modulation" ignores the facts and remarks on the record regarding the Office's own references.

MPEP 2144.03 and controlling case law (e.g., *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); and, *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970) require the Office to provide reasonable support for allegations of what one of skill would "recognize". Here, Applicants have pointed out that the facts in the references are contrary to the rationale in the rejection. Still, the Action repeats the refuted allegations without addressing the facts provided by Applicants in prior Responses. Therefore, the Office fails to state a case because the unrebutted facts on record show that not all cancer patients are in need of immune modulation.

Because not all cancer patients are in need of immune response modulation, identification of cancer patients as a group does not identify an individual in need of immune response modulation. Because Grassetti '364 does not teach at least identifying an individual in need of immune response modulation, the claims can not be considered anticipated and the rejections must be withdrawn.

Grassetti '364 does not inherently administer a TFD to any individual in need of immune response modulation. The Office uses a previously discredited inherency argument to allegedly find Grassetti '364 administering a TFD to an individual identified as in need of immune response modulation. At section 7 of the Action, "Grassetti's method

[allegedly] would have inevitably [inherently] practiced the claimed method ... even [if] the 'in need thereof' is narrowly interpreted as 30% of patients undergoing chemotherapy." Emphasis added. As a preliminary matter, "inevitably" is in the future and can not be cited as a teaching or inherent aspect of the reference at the time. Further, such administration was not inevitable.

Controlling case law requires that a rejection based on an inherency argument must present evidence that the missing descriptive matter is necessarily present in the thing described in the reference. See, e.g., See, *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); and *In re Oelrich* , 666 F.2d 578, 581 - 82, 212 USPQ 323, 326 (CCPA 1981).

The Action, at the top of page 5, allegedly finds the "administering" limitation in Grassetti '364 allegedly teaching "the employment of the same compound for treatment of the same patients with the same amounts ..." However, this is not the case. For example, Grassetti does not describe identifying an individual in need, does not necessarily treat the same patients, and does not necessarily treat with the same amounts (e.g., because the clinical end points may be different).

As a preliminary matter, the allegation clearly does not provide facts showing the Grassetti '364 methods would inevitably practice "identification of an individual in need", as discussed above. In fact, the allegation rests on the contrary scenario provided in which many typical patients must be acknowledged as not in need (as evidenced by, e.g., Tagawa and Barber).

Even if some cancer patients need immune response modulation, the Action has not alleged that any individual patient in Grassetti '364 was actually in need of immune response modulation. That is, an individual patient in need of immune response modulation is not necessarily described in Grassetti '364, and so does not inherently exist in the reference. The Action refers to "massive treatment of patients" but this is aspect drawn out of thin air and not actually practiced in Grassetti '364. Further, even if Grassetti '364 massively treated patients (and he does not), administration of an effective amount of TFD to an individual in need would not necessarily have taken place.

With regard to section 3 of the Action, Applicants note that the aspect of modulating an immune response is not present only in the preamble of the claim. For example, "modulating the immune response" is present in the last clause of independent claim 1.

With regard to section 5 of the Action, concerning *In re Swinehart* and inherent properties of compositions, Applicants direct the Office to remarks of the prior Response of February 7, 2007, at page 8. For example, *Swinehart* is not on point because the rejected method claims are distinguished over the prior art by more than a mere inherent function of compositions in the prior art. That is, the present claims are not limited only to, e.g., a composition of CPDS.

With regard to section 7 of the Action, concerning paragraph [0100] of the present specification, Applicants direct the Office the unaddressed remarks at pages 5 to 7 of the prior Response of July 22, 2008. For example, the logic of the rejection does not require that patients undergoing chemotherapy are in need of immunotherapy just because some patients may have lower than normal numbers of immune cells.

CONCLUSION

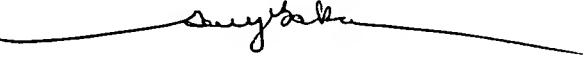
In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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- 1) A transmittal sheet; and,
- 2) A receipt indication postcard.

Respectfully submitted,


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